K063146

510(k) SUMMARY

NOV 2 1 2006

Submission Correspondent: Roche Diagnostics
Address: 9115 Hague Road
Indianapolis, IN 46250

Contact: Scott Thiel
Regulatory Affairs Program Manager
Phone: (800) 428-5074 X 13362
Fax: (317) 521-2324
E Mail: scott.thiel@roche.com

Submission Sponsor: Disetronic Medical Systems AG
Kirchbergstrasse 190, Postfach
CH-3401 Burgdorf
Switzerland

Date Prepared: October 12, 2006

Trade Name: Accu-Chek LinkAssist

Common Name: Spring loaded insertion device

Classification: Introducer, syringe needle

Regulation # 21 CFR 880.6920; Class II device

Product Code KZH

Description:

The Accu-Chek LinkAssist is an insertion aid for automatic application of the Accu-Chek infusion sets with compatible adapter. It permits introduction of the infusion set cannula into the subcutaneous fatty tissue.

The Accu-Chek LinkAssist is made of plastic and stainless steel components and has spring loaded mechanisms. The device is non-invasive, non-sterile and intended for multiple uses by the same patient. The connection between the Accu-Chek LinkAssist device and the infusion set is established by means of a compatible sterile adapter.

Intended Use:
The Accu-Chek LinkAssist is an insertion device, which is intended specifically for placement of compatible Accu-Chek infusion sets.

Predicate Devices:

The Accu-Chek LinkAssist is substantially equivalent to the following predicate devices:

- Sof-Serter by Medtronic Minimed; 510(k) number K970479
- Quick-Serter by Medtronic Minimed, 510(k) number K992300

Safety and Effectiveness:

The Accu-Chek LinkAssist device and the predicate devices, Sof-Serter and Quick-Serter, have the same intended use and are for multiple uses with dedicated infusion sets. All devices are made of plastics and metal springs and have similar method of operations which employ spring loaded mechanisms.

Performance and functional testing of the Accu-Chek LinkAssist have been verified and validated and no new issues were raised regarding safety and effectiveness.

Summary and Conclusion Regarding Substantial Equivalence:

By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics, but it can be demonstrated that the device is as safe and effective as the predicate device and the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device.

The Accu-Chek LinkAssist has the same indications for use and has similar method of operations, which employ spring loaded mechanisms as the above predicate devices. Based on the design equivalency and the testing performed, we have determined that the Accu-Chek LinkAssist is substantially equivalent to the predicate device(s) currently on the market.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 27 2006

Disetronic Medical Systems AG
C/O Mr. Scott Thiel
Regulatory Affairs Program Manager
Roche Diagnostics
9115 Hague Road
Indianapolis, Indiana 46250

Re: K063146
Trade/Device Name: Accu-Chek LinkAssist
Regulation Number: 21 CFR 880.6920
Regulation Name: Syringe Needle Introducer
Regulatory Class: II
Product Code: KZH
Dated: October 12, 2006
Received: October 16, 2006

Dear Mr. Thiel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): _____

Device Name: Accu-Chek LinkAssist

The Accu-Chek LinkAssist is an insertion device, which is intended specifically for placement of compatible Accu-Chek infusion sets.

Prescription Use _X___ OR Over the Counter Use_____
(Per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE -CONTINUE ON ANOTHER PAGE IF NEEDED)

[illegible]
[illegible] of Anesthesiology, General Hospital,
[illegible]ion Control, Dental Devices
[illegible] K063146